

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

STRITTMATTER *et al.*

Appl. No.: 10/553,669 (U.S. National  
Phase of PCT/US2004/011728)

Int'l Filing Date: April 16, 2004

For: **Nogo-Receptor Antagonists for  
the Treatment of Conditions  
Involving Amyloid Plaques**

Confirmation No.: 4039

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 2159.0470001/EJH/SAC

**Information Disclosure Statement  
Filing Under 37 C.F.R. § 1.97(b)**

***Mail Stop Amendment***

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents **FP1** to **FP21** and **NPL1** to **NPL43** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents **US1** to **US31**, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language document **FP10** cited on Form PTO/SB/08A:

Document FP10, WO 93/01288 A1, is in a foreign language. The relevance of document **FP10** may be found in the English language abstract included on the face page of said document.

The Examiner's attention is directed to the following U.S. Patent Applications and PCT Patent Applications, which are directed to related technical subject matter:

U.S. Patent Application No. 09/758,140 inventor Strittmatter S.M., filed January 12, 2001; published as US 2002/0012965 A1, cited herein as document **US22**;

U.S. Patent Application No. 09/972,599, inventor Strittmatter S.M., filed October 6, 2001; published as US2002/0077295 A1, cited herein as document **US24**;

U.S. Patent Application No. 09/972,546, inventors Strittmatter *et al.*, filed October 6, 2001; published as US2003/0124704 A1, cited herein as document **US27**;

U.S. Patent Application No. 10/735,256, inventors Strittmatter *et al.*, filed December 12, 2003; published as US2005/0048520 A1, cited herein as document **US29**;

U.S. Patent Application No. 11/055,163, inventors Lee *et al.*, February 10, 2005; published as US2005/0271655 A1, cited herein as document **US31**;

PCT Patent Application No. PCT/US01/01041, applicant Yale University, filed January 12, 2001, published as WO 01/51520 A2, cited herein as document **FP14**;

PCT Patent Application No. PCT/US01/31488, applicants Yale University and Biogen, Inc., filed October 06, 2001, published as WO 02/29059 A2, cited herein as document **FP15**;

PCT Patent Application No. PCT/US02/32007, applicant Yale University, filed October 04, 2002, published as WO 03/031462 A2, cited herein as document **FP17**;

PCT Patent Application No. PCT/US2003/025004, applicant Yale University and Biogen, Inc., filed August 07, 2003, published as WO 04/014311 A2, cited herein as document **FP19**;

PCT Patent Application No. PCT/US2004/011728, applicants and inventors Strittmatter *et al.*, filed April 16, 2004, published as WO 04/093893 A2, cited herein as document **FP20**; and

PCT Patent Application No. PCT/US04/002702, applicants and inventors Lee *et al.*, filed January 30, 2004, published as WO 05/016955 A2, cited herein as document **FP21**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent

application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Registration No. 58,240

Date:

September 5, 2006

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/553,669 ( <i>U.S. National Phase of PCT/US2004/011728</i> )
				I.A. Filing Date	April 16, 2004
				First Named Inventor	Strittmatter, Stephen M.
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	1	of	2	Attorney Docket Number	2159.0470001/EJH/SAC

U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code <sup>2</sup> (if known)		
	US1	3,817,837	06/18/1974	Rubenstein <i>et al.</i>
	US2	3,850,752	11/26/1974	Schuurs <i>et al.</i>
	US3	3,939,350	02/17/1976	Kronick <i>et al.</i>
	US4	3,996,345	12/07/1976	Ullman <i>et al.</i>
	US5	4,275,149	06/23/1981	Litman <i>et al.</i>
	US6	4,277,437	07/07/1981	Maggio
	US7	4,366,241	12/28/1982	Tom <i>et al.</i>
	US8	4,399,216	08/16/1983	Axel <i>et al.</i>
	US9	4,510,245	04/09/1985	Cousens <i>et al.</i>
	US10	4,634,665	01/06/1987	Axel <i>et al.</i>
	US11	4,816,567	03/28/1989	Cabilly <i>et al.</i>
	US12	4,968,615	11/06/1990	Koszinowski <i>et al.</i>
	US13	5,168,062	12/01/1992	Stinski
	US14	5,179,017	01/12/1993	Axel <i>et al.</i>
	US15	5,223,409	06/29/1993	Ladner <i>et al.</i>
	US16	5,877,293	03/02/1999	Adair <i>et al.</i>
	US17	5,886,152	03/23/1999	Nakatani <i>et al.</i>
	US18	6,054,297	04/25/2000	Carter <i>et al.</i>
	US19	6,475,753 B1	11/05/2002	Ruben <i>et al.</i>
	US20	6,627,741 B2	09/30/2003	Ruben <i>et al.</i>

FOREIGN PATENT DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>2</sup> (if known)		
	FP1	EP 0 216 846 B1	01/10/1990	CellTech Limited
	FP2	EP 0 256 055 B1	08/28/1991	CellTech Limited
	FP3	EP 0 323 997 B1	04/21/1993	CellTech Limited
	FP4	WO 91/17271 A1	11/14/1991	Affymax Technologies N.V.
	FP5	WO 92/01047 A1	01/23/1992	Cambridge Antibody Technology Limited
	FP6	WO 92/09690 A2	06/11/1992	Genentech, Inc.
	FP7	WO 92/15679 A1	09/17/1992	Protein Engineering Corporation
	FP8	WO 92/18619 A1	10/29/1992	The Scripps Research Institute
	FP9	WO 92/20791 A1	11/26/1992	Cambridge Antibody Technology Limited
	FP10	WO 93/01288 A1	01/21/1993	Deutsches Krebsforschungszentrum Stiftung Des Öffentlichen Rechts
	FP11	WO 99/27944 A1	06/10/1999	Neuralab Limited
	FP12	WO 00/72876 A2	12/07/2000	Neuralab Limited

Examiner Signature		Date Considered	
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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## FOREIGN PATENT DOCUMENTS

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Sheet	1	of	5	Attorney Docket Number	2159.0470001/EJH/SAC

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL1	Bard, F., <i>et al.</i> , "Peripherally administered antibodies against amyloid $\beta$ -peptide enter the central nervous system and reduce pathology in a mouse model of Alzheimer disease," <i>Nat. Med.</i> 6:916-919, Nature Publishing Company (August 2000)	
	NPL2	Basso, D.M., <i>et al.</i> , "MASCIS Evaluation of Open Field Locomotor Scores: Effects of Experience and Teamwork on Reliability," <i>J. Neurotrauma</i> 13:343-359, Mary Ann Liebert, Inc. (November 1996)	
	NPL3	Brittis, P.A. and Flanagan, J.G., "Nogo Domains and a Nogo Receptor: Implications for Axon Regeneration," <i>Neuron</i> 30:11-14, Cell Press (April 2001)	
	NPL4	Chen, M.S., <i>et al.</i> , "Nogo-A is a myelin-associated neurite outgrowth inhibitor and an antigen for monoclonal antibody IN-1," <i>Nature</i> 403:434-439, Macmillan Magazines Ltd. (2000)	
	NPL5	Domeniconi, M., <i>et al.</i> , "Myelin-Associated Glycoprotein Interacts with the Nogo66 Receptor to Inhibit Neurite Outgrowth," <i>Neuron</i> 35:283-290, Cell Press (July 2002)	
	NPL6	Fournier, A.E., <i>et al.</i> , "Identification of a receptor mediating Nogo-66 inhibition of axonal regeneration," <i>Nature</i> 409:341-346, Macmillan Magazines Ltd. (January 2001)	
	NPL7	Fournier, A.E., <i>et al.</i> , "Characterization of the neuronal receptor mediating Nogo-66 inhibition of axonal regeneration," <i>J. Neurochem.</i> 78 (Suppl. 1):105, Blackwell Publishing, Abstract No. S08-01 (September 2001)	
	NPL8	Fournier, A.E., <i>et al.</i> , "Nogo Receptor Domain Analysis," <i>Society for Neuroscience Abstracts</i> 27:670, Society for Neuroscience, Abstract No. 258.3, presented at the <i>Society for Neuroscience's 31st Annual Meeting</i> , San Diego, CA (November 12, 2001)	
	NPL9	Fournier, A.E., <i>et al.</i> , "Truncated Soluble Nogo Receptor Binds Nogo-66 and Blocks Inhibition of Axon Growth by Myelin," <i>J. Neurosci.</i> 22:8876-8883, Society of Neuroscience with the assistance of Stanford University's HighWire Press <sup>TM</sup> (October 2002)	

Examiner Signature		Date Considered	
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	NPL10	Gill, S.S., <i>et al.</i> , "Direct brain infusion of glial cell line-derived neurotrophic factor in Parkinson disease," <i>Nature Med.</i> 9:589-595, Nature Publishing Company (May 2003)	
	NPL11	Grandpré, T., <i>et al.</i> , "Identification of the Nogo inhibitor of axon regeneration as a Reticulon protein," <i>Nature</i> 403:439-444, Macmillan Magazines Ltd. (January 2000)	
	NPL12	GrandPre, T.J., <i>et al.</i> , "Functional Analysis of Nogo-66 and Nogo Receptor Domains," <i>Society for Neuroscience Abstracts</i> 27:670, Society for Neuroscience, Abstract No. 258.4, presented at the <i>Society for Neuroscience's 31st Annual Meeting</i> , San Diego, CA (November 12, 2001)	
	NPL13	Grandpré, T., <i>et al.</i> , "Nogo-66 receptor antagonist peptide promotes axonal regeneration," <i>Nature</i> 417:547-551, Nature Publishing Group (May 2002)	
	NPL14	Grimpe, B., <i>et al.</i> , "The Critical Role of Basement Membrane-Independent Laminin $\gamma$ 1 Chain during Axon Regeneration in the CNS," <i>J. Neurosci.</i> 22:3144-3160, Society for Neuroscience with the assistance of Stanford University's HighWire Press™ (April 2002)	
	NPL15	Holtzman, D.M., <i>et al.</i> , "Abeta immunization and anti-Abeta antibodies: potential therapies for the prevention and treatment of Alzheimer's disease," <i>Adv. Drug Deliv. Rev.</i> 54:1603-1613, Elsevier Science Publishers, B.V. (December 2002)	
	NPL16	Jones, L.L., <i>et al.</i> , "NG2 Is a Major Chondroitin Sulfate Proteoglycan Produced after Spinal Cord Injury and Is Expressed by Macrophages and Oligodendrocyte Progenitors," <i>J. Neurosci.</i> 22:2792-2803, Society for Neuroscience with the assistance of Stanford University's HighWire Press™ (April 2002)	
	NPL17	Li, M., <i>et al.</i> , "Functional Role and Therapeutic Implications of Neuronal Caspase-1 and -3 in a Mouse Model of Traumatic Spinal Cord Injury," <i>Neurosci.</i> 99:333-342, Elsevier Science Ltd. (2000)	
	NPL18	Li, M., <i>et al.</i> , "Effect of soluble Nogo receptor treatment on functional and histological outcome after spinal cord injury in the rat," Biosis Database, Accession No. PREV200400194121, Abstract No. 80.22, <i>Presented at the 33rd Annual Meeting of the Society of Neuroscience</i> , New Orleans, LA (November 8-12, 2003)	

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	NPL19	Li, S. and Strittmatter, S.M., "Delayed Systemic Nogo-66 Receptor Antagonist Promotes Recovery from Spinal Cord Injury," <i>J. Neurosci.</i> 23:4219-4227, Society for Neuroscience with the assistance of Stanford University's HighWire Press™ (May 2003)	
	NPL20	Li, W., <i>et al.</i> , "A Neutralizing Anti-Nogo66 Receptor Monoclonal Antibody Reverses Inhibition of Neurite Outgrowth by Central Nervous System Myelin," <i>J. Biol. Chem.</i> 42:43780-43788, The American Society for Biochemistry and Molecular Biology, Inc. (October 2004)	
	NPL21	Li, W., <i>et al.</i> , "Neutralization of NGR1 May Be Sufficient to Promote Rat DRG Neurite Outgrowth in the Presence of CNS Myeline," SFN 2003 Abstract Viewer & Itinerary Planner, Program No. 678.3, <i>Presented at the 33rd Annual Meeting of the Society of Neuroscience</i> , New Orleans, LA (November 8-12, 2003)	
	NPL22	Liu, B.P., <i>et al.</i> , "Myelin-Associated Glycoprotein as a Functional Ligand for the Nogo-66 Receptor," <i>Science</i> 297:1190-1193, American Association for the Advancement of Science (published online June 27, 2002)	
	NPL23	Liu, Y., <i>et al.</i> , "Transplants of Fibroblasts Genetically Modified to Express BDNF Promote Regeneration of Adult Rat Rubrospinal Axons and Recovery of Forelimb Function," <i>J. Neurosci.</i> 19:4370-4387, Society for Neuroscience with the assistance of Stanford University's HighWire Press™ (June 1999)	
	NPL24	McGee, A.W. and Strittmatter, S.M., "The Nogo-66 receptor: focusing myelin inhibition of axon regeneration," <i>Trends Neurosci.</i> 26:193-198, Elsevier Science Ltd. (April 2003)	
	NPL25	McKerracher, L., <i>et al.</i> , "Identification of Myelin-Associated Glycoprotein as a Major Myelin-Derived Inhibitor of Neurite Growth," <i>Neuron</i> 13:805-811, Cell Press (October 1994)	
	NPL26	Metz, G.A.S., <i>et al.</i> , "Efficient testing of motor function in spinal cord injured rats," <i>Brain Res.</i> 883:165-177, Elsevier Science B.V. (2000)	
	NPL27	Mikol, D.D. and Stefansson, K., "A Phosphatidylinositol-linked Peanut Agglutinin-binding Glycoprotein in Central Nervous System Myelin and on Oligodendrocytes," <i>J. Cell. Biol.</i> 106:1273-1279, The Rockefeller University Press (1988)	

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Sheet	4	of	5	Attorney Docket Number	2159.0470001/EJH/SAC
	NPL28	Mukhopadhyay, G., <i>et al.</i> , "A Novel Role for Myelin-Associated Glycoprotein as an Inhibitor of Axonal Regeneration," <i>Neuron</i> 13:757-767, Cell Press (1994)			
	NPL29	Nakamura, F., <i>et al.</i> , "Neuropilin-1 Extracellular Domains Mediate Semaphorin D/III-Induced Growth Cone Collapse," <i>Neuron</i> 21:1093-1100, Cell Press (1998)			
	NPL30	Noël, D., <i>et al.</i> , "High <i>In Vivo</i> Production of a Model Monoclonal Antibody on Adenoviral Gene Transfer," <i>Human Gene Therapy</i> 13:1483-1493, Mary Ann Liebert, Inc. (August 2002)			
	NPL31	Oertle, T., <i>et al.</i> , "Nogo-A Inhibits Neurite Outgrowth and Cell Spreading with Three Discrete Regions," <i>J. Neurosci.</i> 23:5393-5406, Society for Neuroscience (July 2003)			
	NPL32	Park, J.H., <i>et al.</i> , "Alzheimer Precursor Protein Interaction with the Nogo-66 Receptor Reduces Amyloid- $\beta$ Plaque Desposition," <i>J. Neurosci.</i> 26:1386-1395, Society for Neuroscience (February 2006)			
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	NPL34	Ramon-Cueto, A., <i>et al.</i> , "Functional Recovery of Paraplegic Rats and Motor Axon Regeneration in Their Spinal Cords by Olfactory Ensheathing Glia," <i>Neuron</i> 25:425-435, Cell Press (February 2000)			
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	NPL38	Wang, H.-Y., <i>et al.</i> , "Amyloid Peptide A $\beta$ <sub>1-42</sub> Binds Selectively and with Picomolar Affinity to $\alpha$ 7 Nicotinic Acetylcholine Receptors," <i>J. Neurochem.</i> 75:1155-1161, Lippincott Williams & Wilkins, Inc. (2000)			

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				Application Number	10/553,669 ( <i>U.S. National Phase of PCT/US2004/011728</i> )
				I.A. Filing Date	April 16, 2004
				First Named Inventor	Strittmatter, Stephen M.
				Art Unit	To be assigned
				Examiner Name	To be assigned
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	NPL39	Weidner, N., <i>et al.</i> , "Spontaneous corticospinal axonal plasticity and functional recovery after adult central nervous system injury," <i>Proc. Natl. Acad. Sci. USA</i> 98:3513-3518, The National Academy of Sciences (March 2001)			
	NPL40	International Search Report for International Application No. PCT/US2004/011728, European Patent Office, Netherlands, mailed December 6, 2004			
	NPL41	International Search Report for International Application No. PCT/US2005/002535, European Patent Office, Netherlands, mailed October 24, 2005			
	NPL42	International Search Report for International Application No. PCT/US05/35719, ISA/US, Alexandria, VA, mailed April 13, 2006			
	NPL43	International Search Report for International Application No. PCT/US2004/02702, ISA/US, Alexandria, VA, mailed April 20, 2006			

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